

Serial No. 10/759,904
ERIC J. BECKMAN et al.

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AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings in the application:

1. (Currently amended) A biodegradable and biocompatible polyurethane composition synthesized by:

reacting isocyanate groups of at least one multifunctional isocyanate compound, wherein the multifunction isocyanate compound is formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups, with at least one bioactive agent having at least one reactive group -X which is a hydroxyl group (-OH) or an amine group (-NH₂), the polyurethane composition being biodegradable within a living organism to release biocompatible degradation products including the bioactive agent, the released bioactive agent affecting at least one of biological activity or chemical activity in the host organism, wherein the bioactive agent is an enzyme, an organic catalyst, a ribozyme, an organometallic, a protein, a glycoprotein, a lipoprotein, a peptide, a polyamino acid, an antibody, a nucleic acid, a steroid molecule, an antibiotic, an antiviral, an antimycotic, an anticancer agent, an immunosuppressant, a cytokine, a carbohydrate, an oleophobic, a lipid, an extracellular matrix, a component of an extracellular matrix, a chemotherapeutic agent, an anti-rejection agent, an analgesic agent, an anti-inflammatory agent, a hormone, a virus, a viral vector, a vireno, or a prion.

2. (Cancel) The composition of Claim 1 wherein the multifunction isocyanate compound is formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups.

3. (Original) The composition of Claim 2 wherein the bioactive agent has at least two reactive groups -X and -X¹ which are independently the same or different a hydroxyl group (-OH) or an amine group (-NH₂).

4. (Previously presented) The composition of Claim 3 wherein the multifunctional isocyanate compound is also reacted with at least one biocompatible polyol compound, the polyol compound having at least two reactive groups -X² and -X³ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂).

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5. (Previously presented) The composition of Claim 4 wherein the multifunctional isocyanate is also reacted with at least one biocompatible chain extender, the chain extender, wherein the chain extender is water or a compound having at least two reactive groups -X⁴ and -X⁵ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂).

6. (Previously presented) The composition of Claim 4 wherein the multifunctional isocyanate compound, the bioactive agent and the polyol compound are reacted to form a prepolymer, the prepolymer being further reacted with at least one biocompatible chain extender, wherein the chain extender is water or a compound having at least two reactive groups -X⁴ and -X⁵ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂).

7. (Previously presented) The composition of Claim 1 wherein the multifunctional isocyanate compound is a prepolymer formed by the reaction of a multifunctional isocyanate precursor and at least one biocompatible polyol compound, the polyol compound having at least two reactive groups -X² and -X³ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂), the multifunction isocyanate precursor being formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups.

8. (Original) The composition of Claim 7 wherein the prepolymer is contacted with the bioactive agent.

9. (Previously presented) The composition of Claim 8 wherein the bioactive compound is in a solution with at least one biocompatible chain extender, wherein the chain extender is water or a compound having at least two reactive groups -X⁴ and -X⁵ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂).

10. (Original) The composition of Claim 1 wherein the bioactive agent has a therapeutic effect in the organism upon release.

11. (Previously presented) The composition of Claim 1 wherein the bioactive agent is an organic catalyst, a protein, a glycoprotein, a lipoprotein, a peptide, a polyamino acid, a steroid molecule, an antibiotic, an antiviral, an antimycotic, an anticancer agent, an immunosuppressant, a cytokine, a lipid, an extracellular matrix, a component of an extracellular

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matrix, a chemotherapeutic agent, an anti-rejection agent, an analgesic agent, an anti-inflammatory agent, or a hormone.

12. (Original) The composition of Claim 7 where the multifunctional isocyanate precursor is an aliphatic multifunctional isocyanate.

13. (Withdrawn) The composition of Claim 7 where the multifunctional isocyanate precursor is derived from a biomolecule.

14. (Withdrawn) The composition of Claim 13 where the multifunctional isocyanate precursor is derived from an amino acid.

15. (Original) The composition of Claim 7 where the polyol compound is a biomolecule.

16. (Original) The composition of Claim 15 where the polyol compound is a hydroxylated biomolecule.

17. (Withdrawn) The composition of Claim 9 where the chain extender is a biomolecule.

18. (Original) The composition of Claim 9 where the chain extender is water.

19. (Original) The composition of Claim 1 where the bioactive agent has amine and/or hydroxyl functionality greater than or equal to two.

20. The composition of Claim 1 where the bioactive agent has a molecular weight ranging from 10 to 1,000,000 g/mol.

21. (Original) The composition of Claim 10 where the bioactive agent has inductive capacity for restoration of tissue.

22. (Original) The composition of Claim 1 where the polyurethane is a porous foam.

23. (Original) The composition of Claim 22 where the diameter of the pores is in the range of approximately 50 μ m to approximately 500 μ m.

24. (Original) The composition of Claim 7 where the prepolymer has a free isocyanate content of 1 – 32 wt-%.

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25. (Original) The composition of Claim 7 where the prepolymer is synthesized at an NCO:OH equivalent ratio greater than unity.

26. (Original) The composition of Claim 7 where the prepolymer is synthesized at an NCO:OH equivalent ratio in the range of approximately 1 to approximately 2.

27. (Currently amended) A method for the synthesis of a biodegradable, biocompatible, and bioactive polyurethane composition comprising the step:

reacting isocyanate groups of at least one multifunctional isocyanate compound, wherein the multifunction isocyanate compound is formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups, with at least one bioactive agent having at least one reactive group -X which is a hydroxyl group (-OH) or an amine group (-NH₂), the polyurethane composition being biodegradable within a living organism to release biocompatible degradation products including the bioactive agent, the released bioactive agent affecting at least one of biological activity or chemical activity in the host organism, wherein the bioactive agent is an enzyme, an organic catalyst, a ribozyme, an organometallic, a protein, a glycoprotein, a lipoprotein, a peptide, a polyamino acid, an antibody, a nucleic acid, a steroid molecule, an antibiotic, an antiviral, an antimycotic, an anticancer agent, an immunosuppressant, a cytokine, a carbohydrate, an oleophobic, a lipid, an extracellular matrix, a component of an extracellular matrix, a chemotherapeutic agent, an anti-rejection agent, an analgesic agent, an anti-inflammatory agent, a hormone, a virus, a viral vector, a vireno, or a prion.

28. (Original) The method of Claim 27 wherein the multifunction isocyanate compound is formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups.

29. (Original) The method of Claim 28 wherein the bioactive agent has at least two reactive groups -X and -X¹ which are independently the same or different a hydroxyl group (-OH) or an amine group (-NH₂).

30. (Previously presented) The method of Claim 29 wherein the multifunctional isocyanate compound is also reacted with at least one biocompatible polyol compound, the polyol compound having at least two reactive groups -X² and -X³ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂).

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31. (Previously presented) The method of Claim 30 wherein the multifunctional isocyanate is also reacted with at least one biocompatible chain extender, wherein the chain extender is water.

32. (Previously presented) The method of Claim 30 wherein the multifunctional isocyanate compound, the bioactive agent and the polyol compound are reacted to form a prepolymer, the prepolymer being further reacted with at least one biocompatible chain extender, wherein the chain extender is water or a compound having at least two reactive groups -X⁴ and -X⁵ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂).

33. (Previously presented) The method of Claim 27 wherein the multifunctional isocyanate compound is a prepolymer formed by the reaction of a multifunctional isocyanate precursor and at least one biocompatible polyol compound, the polyol compound having at least two reactive groups -X² and -X³ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂), the multifunction isocyanate precursor being formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups.

34. (Previously presented) The method of Claim 27 wherein the bioactive agent is dissolved in at least one biocompatible chain extender, wherein the chain extender is water.

35. (Original) The method of Claim 34 wherein the solution of the bioactive agent and the chain extender is contacted with the prepolymer to form the polyurethane.

36. (Original) The method of Claim 35 where the prepolymer has a free isocyanate content of 1 - 32 wt-%.

37. (Original) The method of Claim 35 where the prepolymer is synthesized at an NCO:OH equivalent ratio greater than unity.

38. (Original) The method of Claim 35 where the prepolymer is synthesized at an NCO:OH equivalent ratio in the range of approximately 1 to approximately 2.

39. (Original) The method of Claim 35 where the chain extender is water.

40. (Withdrawn) A method of synthesizing a bone tissue engineering scaffold including the steps of:

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coating a biodegradable and bioactive polyurethane polymer with human osteoblastic precursor cells, the polymer being synthesized by reacting isocyanate groups of at least one multifunctional isocyanate compound with at least one bioactive agent having at least one reactive group -X which is a hydroxyl group (-OH) or an amine group (-NH₂), the polyurethane being biodegradable within a living organism to biocompatible degradation products including the bioactive agent, the released bioactive agent affecting at least one of biological activity or chemical activity in the host organism; and

culturing the osteoblastic precursor cells under conditions suitable to promote cell growth.

41. (Withdrawn) The method of Claim 40 wherein, prior to coating the osteoblastic precursor cells upon the biocompatible, biodegradable polyurethane, the polyurethane is synthesized by the steps:

reacting at least one multifunctional isocyanate precursor compound with at least one biocompatible polyol compound, the polyol compound having at least two reactive groups -X² and -X³ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂) to form the multifunctional isocyanate compound, which is an isocyanate-terminated prepolymer, the multifunction isocyanate precursor compound being formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups;

sterilizing the isocyanate-terminated prepolymer,

dissolving the bioactive agent in at least one sterile chain extender, the bioactive agent having at least two reactive groups -X and -X¹ which are independently the same or different a hydroxyl group (-OH) or an amine group (-NH₂), wherein the chain extender is water or a compound having at least two reactive groups -X⁴ and -X⁵ which are independently the same or different hydroxyl group (-OH) or an amine group (-NH₂); and

contacting the isocyanate-terminated prepolymer with the solution of the bioactive agent and the chain extender to form a polyurethane bone tissue engineering scaffold.

42. (Withdrawn) The method of Claim 41 where the prepolymer has a free isocyanate content of 1 - 32 wt-%.

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43. (Withdrawn) The method of Claim 41 where the prepolymer is synthesized at an NCO:OH equivalent ratio greater than unity.
44. (Withdrawn) The method of Claim 41 where the prepolymer is synthesized at an NCO:OH equivalent ratio greater than or equal to two.
45. (Withdrawn) The method of Claim 41 where the chain extender is water to create a foamed polyurethane.
46. (Withdrawn) The method of Claim 45 wherein the bioactive agent has a therapeutic effect in the organism upon release.
47. (Withdrawn) The method of Claim 41 wherein the bioactive agent is an enzyme, an organic catalysts a ribozyme, an organometallic, a protein, a glycoprotein, a lipoprotein, a peptide, a polyamino acid, an antibody, a nucleic acid, a steroid molecule, an antibiotic, an antiviral, an antimycotic, a cytokine, a carbohydrate, an oleophobic, a lipid, an extracellular matrix, a component of an extracellular matrix, a chemotherapeutic agent, an anti-rejection agent, an analgesic agent, an anti-inflammatory agent, a hormone, a virus, a viral vector, a vireno, or a prion.
48. (Withdrawn) The method of Claim 46 wherein the bioactive agent is a growth factor.
49. The method of Claim 46 wherein the bioactive agent is ascorbic acid.
50. (Withdrawn) The method of Claim 46 wherein the multifunctional isocyanate precursor compound is an aliphatic multifunctional isocyanate.
51. (Withdrawn) The method of Claim 46 wherein the multifunctional amine compound from which the multifunctional isocyanate precursor compound is derived is a biomolecule or a biocompatible derivative of a biomolecule.
52. (Withdrawn) The method of Claim 51 wherein the multifunctional amine compound is an amino acid or a biocompatible derivative of an amino acid.
53. (Withdrawn) The method of Claim 51 wherein the multifunctional amine compound is lysine, lysine ethyl ester, lysine methyl ester, putrescine, arginine, glutamine or histidine.

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54. (Withdrawn) The method of Claim 51 wherein the multifunctional amine compound is a biocompatible diester diamine derived from biomolecules or a biomolecule and a biocompatible diol.

55. (Withdrawn) The method of Claim 51 wherein the polyol compound is a biomolecule or a biocompatible derivative of a biomolecule.

56. (Withdrawn) The method of Claim 51 wherein the polyol compound is a hydroxylated biomolecule.

57. (Withdrawn) The method of Claim 51 wherein the polyol is a polyether, polytetramethylene etherglycol, polypropylene oxide glycol, polyethylene oxide glycol, a polyester, polycaprolactone, a polycarbonate, a saccharide, a polysaccharide, castor oil, a hydroxylated fatty acid, a hydroxylated triglyceride, or a hydroxylated phospholipids.

58. (Withdrawn) The method of Claim 51 where at least one chain extender, which is a biomolecule, is reacted with the prepolymer.

59. (Withdrawn) A method of delivering a bioactive agent into an organism comprising the steps:

injecting at least one multifunctional isocyanate compound into the organism;

injecting at least one bioactive agent into the organism, having at least two reactive groups -X and -X¹ which are, independently the same or different, a hydroxyl group (-OH) or an amine group (-NH₂), the polyurethane composition being biodegradable within a living organism to biocompatible degradation products including the bioactive agent; and

contacting multifunctional isocyanate compound with the bioactive agent to react the isocyanate groups of the multifunctional isocyanate compound with the bioactive agent.

60. (Withdrawn) The method of Claim 59 wherein the multifunction isocyanate compound is formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups.

61. (Withdrawn) The method of Claim 59 further comprising the steps:

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injecting at least one biocompatible polyol compound into the organism, the polyol compound having at least two reactive groups $-X^2$ and $-X^3$ which are independently the same of different hydroxyl group (-OH) or an amine group (-NH₂);

contacting the polyol compound with the multifunctional isocyanate compound within the organism to react the polyol compound with the multifunctional isocyanate compound.

62. (Withdrawn) The method of Claim 61 further comprising the steps:

injecting at least one biocompatible chain extender into the organism, wherein the chain extender is water or a compound having at least two reactive groups $-X^4$ and $-X^5$ which are independently the same of different hydroxyl group (-OH) or an amine group (-NH₂).

63. (Withdrawn) The method of Claim 62 wherein the multifunctional isocyanate compound, the bioactive agent and the polyol compound are reacted to form a prepolymer, the prepolymer being injected separately from the biocompatible chain extender, which is water, and a second biocompatible chain extender, which is a compound wherein $-X^4$ and X^5 are amine groups.

64. (Withdrawn) The method of Claim 59 wherein the multifunctional isocyanate compound is a prepolymer formed by the reaction of a multifunctional isocyanate precursor and the biocompatible polyol compound, the multifunction isocyanate precursor being formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups.

65. (Withdrawn) The method of Claim 64 wherein the prepolymer is injected separately from the bioactive agent.

66. (Withdrawn) The method of Claim 65 wherein the bioactive compound is in a solution with at least one biocompatible chain extender, wherein the chain extender is water or a compound having at least two reactive groups $-X^4$ and $-X^5$ which are independently the same of different hydroxyl group (-OH) or an amine group (-NH₂).

67. (Withdrawn) The method of Claim 66 wherein water and a second chain extender are used, the second chain extender being a compound wherein $-X^4$ and $-X^5$ are amine groups.

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68. (Withdrawn) The method of Claim 61 wherein the bioactive agent, the biocompatible polyol and the biocompatible chain extender are injected as a mixture and the multifunctional isocyanate compound is injected separately.

69. (Currently Amended) An implant for insertion into an organism, the implant being formed external to the organism and subsequently placed into the organism, the implant being formed by reacting isocyanate groups of at least one multifunctional isocyanate compound, wherein the multifunction isocyanate compound is formed via conversion of amine groups of a biocompatible compound having at least two amine groups to isocyanate groups, with at least one bioactive agent having at least one reactive group -X which is a hydroxyl group (-OH) or an amine group (-NH₂), the polyurethane composition being biodegradable within a living organism to release biocompatible degradation products including the bioactive agent, the released bioactive agent affecting at least one of biological activity or chemical activity in the host organism, wherein the bioactive agent is an enzyme, an organic catalysts a ribozyme, an organometallic, a protein, a glycoprotein, a lipoprotein, a peptide, a polyamino acid, an antibody, a nucleic acid, a steroid molecule, an antibiotic, an antivirals, an antimycotic, an anticancer agent, an immunosuppressant, a cytokine, a carbohydrate, an oleophobic, a lipid, an extracellular matrix, a component of an extracellular matrix, a chemotherapeutic agent, an anti-rejection agent, an analgesic agent, an anti-inflammatory agent, a hormone, a virus, a viral vector, a vireno, or a prion.

70. (Withdrawn) A biodegradable polyurethane composition, comprising hard segments and soft segments, each of the hard segments being derived from a diurea diol or a diester diol and being biodegradable into biomolecule degradation products or into biomolecule degradation products and a biocompatible diol.

71. (Withdrawn) The composition of Claim 70 wherein the hard segments comprise groups derived from at least one diisocyanate which results in a diamine biomolecule degradation product upon biodegradation of the polyurethane.

72. (Withdrawn) The composition of Claim 71 wherein diisocyanate groups of the hard segment are derived from butane diisocyanate, lysine diisocyanate, lysine ethyl ester diisocyanate or lysine methyl ester diisocyanate.

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73. (Withdrawn) The composition of Claim 71 wherein the hard segments further comprise at least one group derived from a chain extender.

74. (Withdrawn) The composition of Claim 73 wherein the chain extender is a diurea diol or a diester diamine.

75. (Withdrawn) The composition of Claim 73 wherein the biocompatible diisocyanate is butane diisocyanate, lysine diisocyanate, lysine ethyl ester diisocyanate, or lysine methyl ester diisocyanate.

76. (Withdrawn) The composition of claim 74 wherein the chain extender is a diurea diol wherein one molecule of the biocompatible diisocyanate is reacted with two molecules of a multifunctional biomolecule having a hydroxy group and an amine group.

77. (Withdrawn) The composition of claim 76 wherein the multifunctional biomolecule is tyramine, tyrosine ethyl ester, tyrosine methyl ester, serine ethyl ester, serine methyl ester or pyridoxamine.

78. (Withdrawn) The composition of claim 74 wherein the chain extender is a diester diamine wherein one molecule of a diacid biomolecule is reacted with two molecules of a multifunctional biomolecule having a hydroxy group and an amine group.

79. (Withdrawn) The composition of claim 78 wherein the diacid biomolecule is succinic acid or adipic acid.

80. (Withdrawn) The composition of claim 78 wherein the multifunctional biomolecule is tyramine, tyrosine ethyl ester, tyrosine methyl ester, serine ethyl ester, serine methyl ester or pyridoxamine.

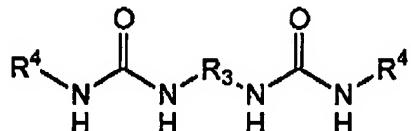
81. (Withdrawn) The composition of claim 74 wherein the chain extender is a diester diamine wherein one molecule of a biocompatible diol is reacted with two molecules of a multifunctional biomolecule having an amine group and a carboxylic acid group or an ester group.

82. (Withdrawn) The composition of claim 81 wherein multifunctional biomolecule is *p*-aminobenzoic acid, ethyl *p*-aminobenzoate, glycine, glycine ethyl ester or glycine methyl ester.

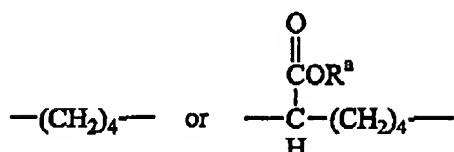
83. (Withdrawn) The composition of claim 81 wherein the biocompatible diol is butanediol.

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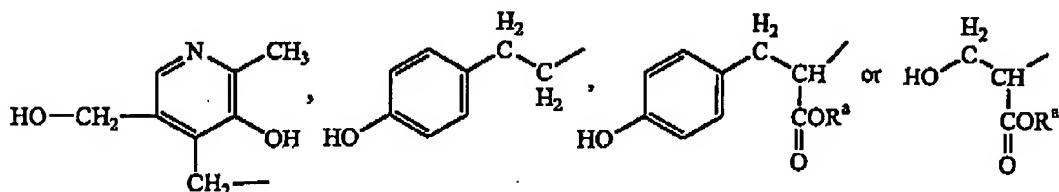
84. (Withdrawn) The composition of Claim 70 wherein the diurea diol has the formula:



wherein R^3 is

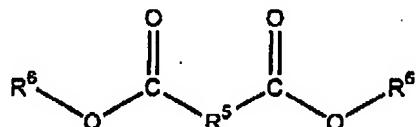


wherein R^4 is



and wherein R^a is -CH₃ or -CH₂CH₃.

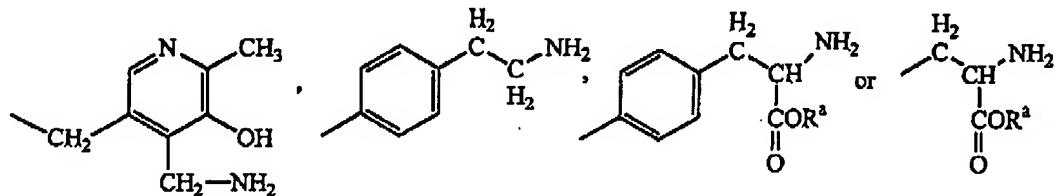
85. (Withdrawn) The composition of Claim 70 wherein the diester diamine has the formula:



wherein R^5 is

$$-(\text{CH}_2)_n-$$

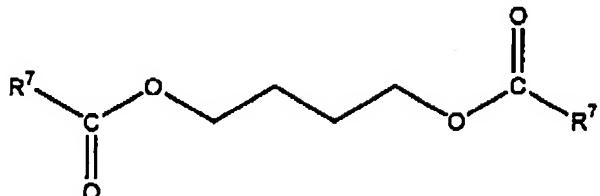
wherein n is 2 or 4, wherein R^6 is



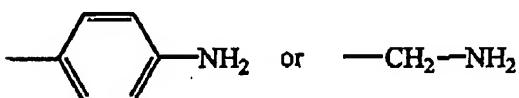
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and wherein R⁸ is -CH₃ or -CH₂CH₃.

86. (Withdrawn) The composition of Claim 70 wherein the diester diamine has the formula:



wherein R⁷



87. (Withdrawn) An implant for use in a living organism, the implant comprising a biodegradable polyurethane composition, comprising hard segments and soft segments, each of the hard segments being derived from a diurea diol or a diester diol and being biodegradable into biomolecule degradation products or into biomolecule degradation products and a biocompatible diol.

88. (Withdrawn) A biodegradable polyurethane composition, comprising hard segments and soft segments, each of the hard segments being derived from a diurethane diol and being biodegradable into biomolecule degradation products.

89. (Withdrawn) The composition of Claim 88 wherein the hard segments comprise groups derived from at least one diisocyanate which results in a diamine biomolecule degradation product upon biodegradation of the polyurethane.

90. (Withdrawn) The composition of Claim 89 wherein diisocyanate groups of the hard segment are derived from butane diisocyanate, lysine diisocyanate, lysine ethyl ester diisocyanate or lysine methyl ester diisocyanate.

91. (Withdrawn) The composition of Claim 89 wherein the hard segments further comprise at least one group derived from a chain extender.

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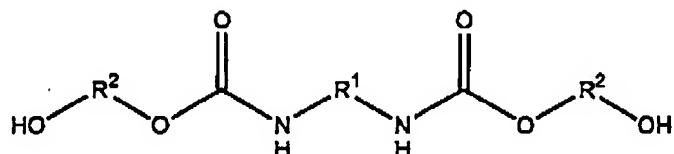
92. (Withdrawn) The composition of Claim 91 wherein the chain extender is a diurethane diol.

93. (Withdrawn) The composition of Claim 90 wherein the biocompatible diisocyanate is butane diisocyanate, lysine diisocyanate, lysine ethyl ester diisocyanate or lysine methyl ester diisocyanate.

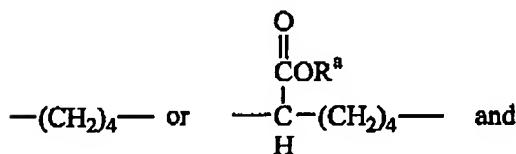
94. (Withdrawn) The composition of claim 91 wherein the chain extender is a diurethane diol wherein one molecule of the biocompatible diisocyanate is reacted with two molecules of a multifunctional biomolecule having two hydroxy groups.

95. (Withdrawn) The composition of claim 91 wherein the multifunctional biomolecule is glyceraldehyde, dihydroxyacetone or pyridoxine.

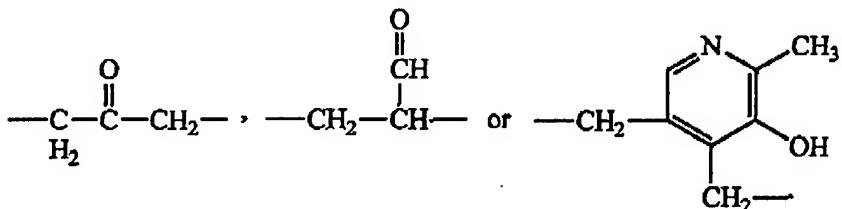
96. (Withdrawn) The composition of Claim 88 wherein the diurethane diol has the formula:



wherein R^1 is



and wherein R^2 is

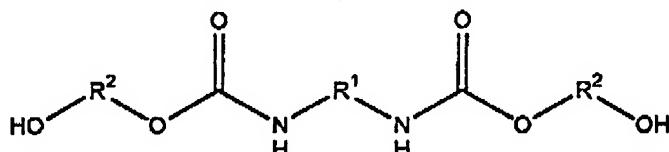


and wherein R^a is $-\text{CH}_3$ or $-\text{CH}_2\text{CH}_3$.

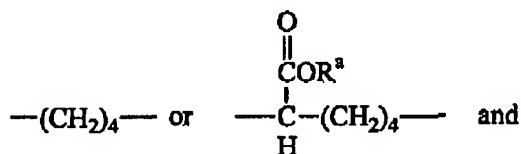
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97. (Withdrawn) An implant for use in a living organism, the implant comprising a biodegradable polyurethane composition, comprising hard segments and soft segments, each of the hard segments being derived from a diurethane diol and is biodegradable into biomolecule degradation products.

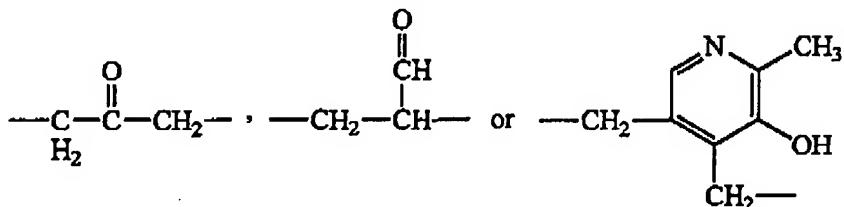
98. (Withdrawn) A composition having the formula:



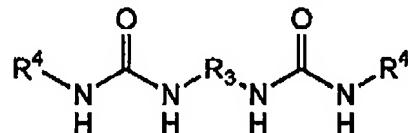
wherein R^1 is



and wherein R^2 is

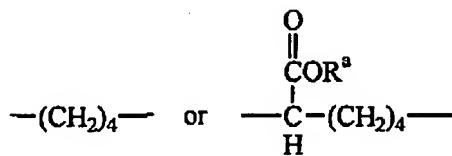


99. (Withdrawn) A composition having the formula:

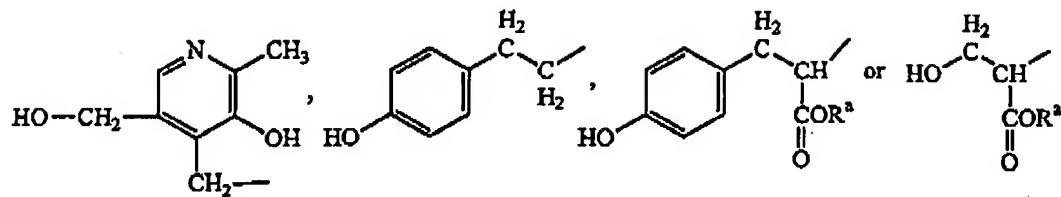


wherein R^3 is

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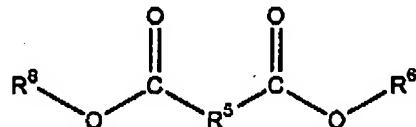


wherein R^4 is



and wherein R^a is $-\text{CH}_3$ or $-\text{CH}_2\text{CH}_3$.

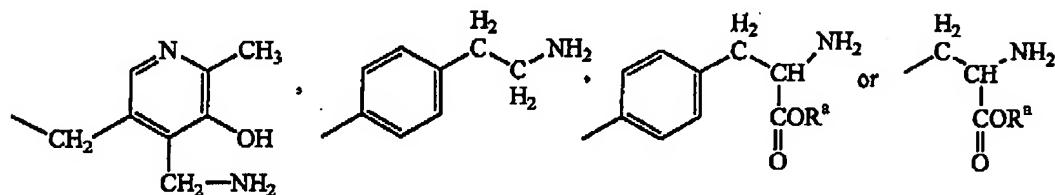
100. (Withdrawn) A composition having the formula:



wherein R^5 is

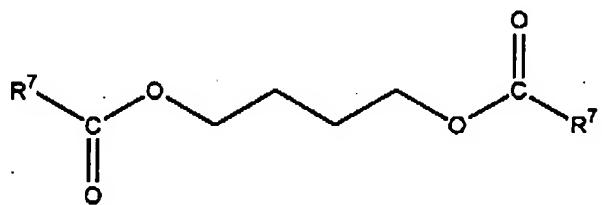


wherein n is 2 or 4, and wherein R^6 is



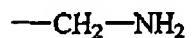
wherein R^a is $-\text{CH}_3$ or $-\text{CH}_2\text{CH}_3$.

101. (Withdrawn) A composition having the formula:

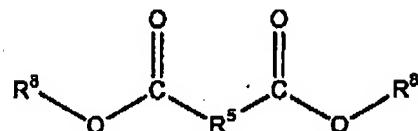


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wherein R^7 is



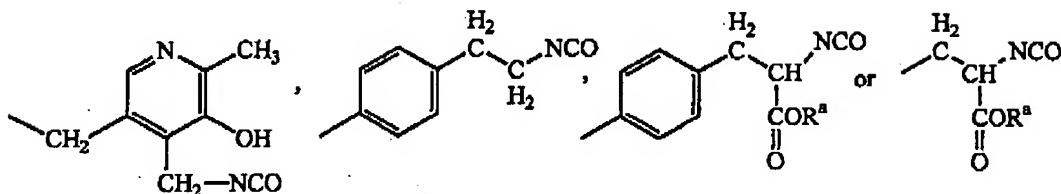
102. (Withdrawn) A composition having the formula:



wherein R^5 is

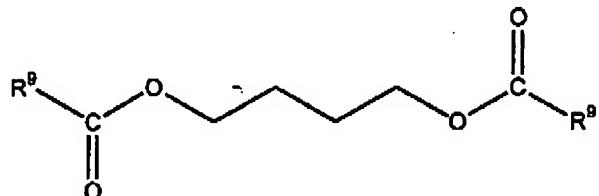


wherein n is 2 or 4, and wherein R^8 is



wherein R^8 is $-\text{CH}_3$ or $-\text{CH}_2\text{CH}_3$.

103. (Withdrawn) A composition having the formula:



wherein R^9 is

